

Serial No. 10/028,258  
Docket No. 0081.02

## REMARKS

### I. Introductory Comments

In the Office Action under reply, the Examiner maintained the claim rejections as follows: under 35 U.S.C. §103(a) as allegedly being unpatentable over Rossling et al. (WO 97/19676) (claims 1-6, 8-17 and 20-30); and under 35 U.S.C. §103(a) as allegedly being unpatentable over Rossling et al. (WO 97/19676) in further view of Setterstrom et al. (U.S. Patent No. 6,410,056) (claims 1-17 and 20-30). The rejections are traversed for reasons provided below.

### II. Amendments to Claims

Claims 1-6 and 8-30 were previously pending in the application. Claims 1, 27 and 28 have been amended without prejudice. No claims have been added. Consequently, claims 1-6 and 8-30 remain pending upon entry of the Amendment.

Support for the amendments is identified below. Additional support other than that identified below may exist in the specification for one or more amendments to the claims.

Claim 1 has been amended to recite specific solvents. Support for the specific solvents now recited in claim 1 can be found on page 18, lines 22-28, of the originally filed specification. Also, support for adding the phrase "without the formation of an intermediate W/O/W double emulsion" is found on page 14, lines 18-20.

Claims 27 and 28 have been amended to provide correct claim syntax by substituting the incorrect word "or" for the correct word -- and --.

As support for the claimed subject matter is found in the application as filed, no new matter is introduced by the entry of the above-identified changes to the claims. The changes to the claims are made for clarification purposes only and should not be interpreted as acquiescence in any claim rejection.

### III. The Rejections Under 35 U.S.C. §103(a)

The Examiner has maintained the rejection of claims 1-6 and 8-30 under 35 U.S.C. §103(a) as being allegedly unpatentable over Rossling et al. (WO 97/19676). In addition, the Examiner

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rejected claims 1-17 and 20-30 as being allegedly unpatentable over Rossling et al. (WO 97/19676) in view of Setterstrom et al. (U.S. Patent No. 6,410,056).

The standard for establishing a *prima facie* case of obviousness was provided in Applicants' previous response.

In the Office Action under reply, the Examiner argues, *inter alia*, that "it would be within the skill of the artisan in the microparticle art to optimize the volumes, and hence solubility parameters, to achieve that recited in the instant claims." Notwithstanding the Examiner's argument, however, the pending claims are patentable in view of the following remarks.

The principle of the invention underlying Rossling et al. is outlined on page 6, line 15, to page 7, line 13. Following the teaching of Rossling et al., the skilled person intending to produce microcapsules will select solvents or solvent mixtures such that a W/O emulsion is first formed from an organic solvent solution of a polymer and an aqueous solution of an active agent. By adding an aqueous surfactant solution, this primary emulsion is transformed into a W/O/W emulsion from which the solvent or solvent mixture is subsequently removed so that the microcapsules are formed.

By contrast, it was first realized in the context of the presently claimed invention that the formation of microparticles can be simplified without impairing the quality of the produced particles when the step of forming a double emulsion is eliminated. To that extent, the claims as well as the specification of the application as filed define water-soluble organic solvents for dissolving the polymer and suitable volume fractions of the aqueous surfactant phase. When an aqueous surfactant phase is added to the drug phase in accordance with the respective teaching given in the application, this will lead to the direct formation of a microparticle suspension.

It is noted that claim 1 (as amended), stipulates that no intermediate W/O/W double emulsion is formed in the process of the presently claimed invention, thereby emphasizing a significant difference between the subject matter of the present claims and the teaching of Rossling et al. In addition, claim 1 (as amended), recites specific solvents to further distinguish the claims over Rossling et al.

Moreover, as the presently claimed invention explicitly requires its particles to be produced without formation of an intermediate W/O/W double emulsion, a significant simplification for the formation of microparticles is achieved. In addition, due to the relative

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short time scale of particle production required by the currently claimed process, an aggregation of the emulsified W/O droplets in the double emulsion can be avoided.

In addition, from Figures 3 and 6 to 10 of the present specification, it can be seen that the modification of the double emulsion process as process in the present invention surprisingly does not affect the quality of the obtained microparticles.

Thus, for at least the above reasons, a *prima facie* cases for rejecting the claims under 35 U.S.C. §103(a) have not been made by the Examiner. Consequently, reconsideration and removal of the rejections is respectfully requested.

#### IV. Conclusion

In view of the foregoing, Applicant submits that the pending claims satisfy the requirements of patentability and are therefore in condition for allowance. Reconsideration and withdrawal rejections is respectfully requested and a prompt mailing of a Notice of Allowance is earnestly solicited.

If a telephone conference would expedite the prosecution of the subject application, the Examiner is requested to call the undersigned at (650) 620-5506.

Respectfully submitted,  
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